

Insert local address

Date: 20.05.2021

Urgent Field Safety Notice
SCS Screwdriver 046.401 (lot EHG85) and 046.402 (lot FAP78)

For Attention of*:ENTER CUSTOMER NAME AND ADDRESS




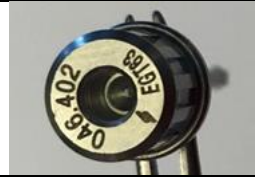



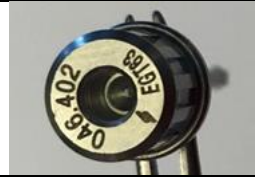



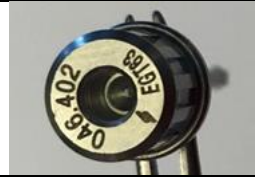
Contact details of local representative (name, e-mail, telephone, address etc.)*
--

ENTER NAME AND ADDRESS OF LOCAL DISTRIBUTION ORGANISATION INCLUDING NAME, TELEPHONE NUMBER AND EMAIL

Urgent Field Safety Notice (FSN)

046.401 SCS Screwdriver for Ratchet, short, length 21 mm (lot EHG85)

046.402 SCS Screwdriver for Ratchet, long, length 27 mm (lot FAP78)

1. Information on Affected Devices*																				
1.	1. Device Type(s)*																			
	<p>The SCS screw drivers are used to tighten restorations on implants/abutments by the ratchet. They are made out of stainless steel and they transmit torque. The tip which is equal for all of them, provides retention to the tightening part and assures aspiration protection. The SCS Screwdrivers are provided non-sterile. According to <i>Straumann Surgical and Prosthetic Instruments, Care and Maintenance (702000/en)</i> All instruments must be cleaned, disinfected and sterilized before every use. This also applies to new instruments removed from protective transport packaging and single-use devices that are delivered non-sterile. Before every use, the device must be carefully checked for proper function and damage</p>																			
1.	2. Commercial name(s)																			
	<p>SCS Screwdriver for Ratchet, short, length 21 mm SCS Screwdriver for Ratchet, long, length 27 mm</p>																			
1.	3. Primary clinical purpose of device(s)*																			
	<p>The Straumann SCS screw drivers for ratchet are used to tighten restorations on implants/abutments by the ratchet. The tip, provides retention to the tightening part and assures aspiration protection.</p>																			
1.	4. Device Model/Catalogue/part number(s)*																			
	<p>046.401 SCS Screwdriver for Ratchet, short, length 21 mm; 046.402 SCS Screwdriver for Ratchet, long, length 27 mm</p>																			
1.	5. Affected Article and lot number																			
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Article Nr</th> <th style="width: 30%;">Description</th> <th style="width: 15%;">Packaged lot number</th> <th style="width: 15%;">Lot Number engraved on part</th> <th style="width: 25%;">Lot number located on head of Screwdriver</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">046.401 </td> <td>SCS Screwdriver for Ratchet, short, length 21 mm</td> <td style="text-align: center;">EHG85</td> <td style="text-align: center;">CXV34</td> <td></td> </tr> <tr> <td style="text-align: center;">046.402 </td> <td>SCS Screwdriver for Ratchet, long, length 27 mm</td> <td style="text-align: center;">FAP78</td> <td style="text-align: center;">EGT63</td> <td></td> </tr> </tbody> </table>					Article Nr	Description	Packaged lot number	Lot Number engraved on part	Lot number located on head of Screwdriver	046.401 	SCS Screwdriver for Ratchet, short, length 21 mm	EHG85	CXV34		046.402 	SCS Screwdriver for Ratchet, long, length 27 mm	FAP78	EGT63	
Article Nr	Description	Packaged lot number	Lot Number engraved on part	Lot number located on head of Screwdriver																
046.401 	SCS Screwdriver for Ratchet, short, length 21 mm	EHG85	CXV34																	
046.402 	SCS Screwdriver for Ratchet, long, length 27 mm	FAP78	EGT63																	

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	<p>Due to a manufacturing error The tip of the SCS Screwdriver the SCS does not have the correct configuration / profile therefore the screwdriver does not properly fit the opposing screw head and cannot pick up the screws. Further functional testing has indicated that while the non-fit /</p>

	function is highly detectable, the SCS Screwdriver can be manipulated using force to pick up the screw/abutment at an angle. This can result in reduced retention between the SCS Screwdriver and attached screw/abutment. This is an isolated issue impacting the below listed articles and lots only.
2.	<p>2. Hazard giving rise to the FSCA</p> <p>The incorrect tip configuration of the SCS screwdriver does not fit to the screw head. Any engagement created with extra force will be insufficient to ensure the retention needed with the screwhead. This can result in reduced retention and reduction in aspiration protection.</p>
2.	<p>3. Probability of problem arising</p> <p>Before every use, the device must be carefully checked for proper function and damage. Under normal use the non-fit of the screwdriver will be detected and not used. If the SCS screwdriver is manipulated to force a connection, the retention between SCS Screwdriver and screw / abutment will be impaired. This could lead to the parts falling into the patients' mouth. Up to date, 1.2% of the affected parts sold led to a customer complaint reporting non fit. No patient or user harm has been reported.</p>
2.	<p>4. Predicted risk to patient/users</p> <p>The risk assessment has determined that due to the high detectability of the defect, the risk of asphyxiation / swallowing is considered remote. None of the received reported complaints have reported any patient or user harm.</p>
2.	<p>5. Background on Issue</p> <p>Institut Straumann has received several complaints from customers that the SCS Screwdriver article 046.401 lot EHG85 and 046.402 lot FAP78 do not fit. The investigation of these complaints has confirmed the tip of the screwdrivers the SCS does not have the correct configuration / profile due to a manufacturing error therefore the screwdriver does not properly fit the opposing screw head and cannot pick up the screws. Further functional testing has indicated that while the non-fit / function is highly detectable, the SCS Screwdriver can be manipulated using force to pick up the screw/abutment at an angle. This can result in reduced retention and reduction in aspiration protection. None of the complaints received by Straumann report that this has happened and no patient harm has occurred. Complaint rate is low (24/ 2'050 = 1.2%) Bounding investigation at the manufacturing site for this event restricts this issue to lots FAP78 and EHG85.</p>

3. Type of Action to mitigate the risk*	
3.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Complete and return the Distributor / Customer Response Form.</p>

3.	2. By when should the action be completed?	Within two weeks of receipt of this notification
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	Action Being Taken by the Manufacturer <input checked="" type="checkbox"/> Removal of impacted lots from market	
3.	4. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information*		
4.	1. FSN Type*	New
4.	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Institut Straumann AG
	b. Address	Peter Merian-Weg 12
	c. Website address	https://www.straumann.com/
	3.	
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. Name/Signature	Insert Name and Title here and signature below

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*</p>